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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,792	08/12/2002	Dangshe Ma	60364A	1289

109 7590 11/24/2004

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER	
HARTLEY, MICHAEL G	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,792	MA ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The amendment filed 10/7/2004 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US 5,756,065) in view of either one of Griffiths (WO 99/30745) or Geerlings (US 5,246,691), for the reasons set forth in the office action mailed 6/8/2004.

Applicant's arguments filed 10/7/2004 have been fully considered but they are not persuasive.

Applicant asserts that given the challenges in finding suitable chelating agent for actinium-225, as described in the prior art, it would not have been obvious to one of ordinary skill in the art to use the chelators disclosed by Wilson with actinium-225.

This is not found persuasive because the chelating portion used to chelate actinium-225 as taught by Griffiths is analogous to that of Wilson, i.e., a DOTA analogue. Wilson teaches the use of DOTA analogues as claimed for binding various metals, including alpha emitters, such as, Bi-212, see column 3. Griffiths teaches that the same macrocyclic chelating functionality as disclosed by Wilson, i.e.. a DOTA analogue is known to be a useful for Ac-225, as well as, the same radiometals disclosed by Wilson (e.g., Sm-153, Ho-166, etc.). Thus, Griffiths teaches the functional equivalence of DOTA chelators for various radiometals, which is the same chelating agent of Wilson. One of ordinary skill in the art of radiopharmaceuticals would expect that analogous chelating agents, such as, the macrocyclic chelate DOTA would have analogous chelating function due to the chemical similarities of the structures, which are basically the same between Wilson and Griffiths, excluding a single side group. Additionally, Geerlings specifically teaches that the chelating agents that bind actinium-225 may be the usual chelating

agents in the art, such as, various chelating agents which are used in a similar fashion as those disclosed by Wilson, see column 1. Thus, one of ordinary skill in the art would have had a reasonable expectation of success that the chelating agents (i.e., DOTA analogues) disclosed by Wilson would chelate Ac-225 to provide the advantages that are known in the art to be a property of Ac-225. Obviousness does not require absolute predictability.

Applicant also asserts that none of the metals disclosed by Wilson are alpha emitters.

This is not found persuasive because Wilson includes Bi-212 which is an alpha emitter.

Applicant asserts the Geerlings does not teach the particular chelating agents as claimed for use with actinium-225.

Geerlings teaches that actinium-225 is a preferred radiometal for radiopharmaceuticals because of its optimal half-life, availability and cytotoxic effect on tumors, and that it can be used with usual chelating agents. One of ordinary skill in the art would have been motivated to use this radiometal in the radiopharmaceutical chelates disclosed by Wilson to obtain is advantageous and desired emissions properties. The cited art does not teach that Ac-225 provides challenges in chelation, but rather provides a general teaching that this radiometal can be chelated using various chelating agents known in the art of radiopharmaceuticals.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US 5,756,065) in view of either one of Griffiths (WO 99/30745) or Geerlings (US 5,246,691), as applied to claims 1-13 and 15-20 above, and further in view of either one of Scheinberg (XP-002194098, PTO-1449) or Co (US 5,714,350), for the reasons set forth in the office action mailed 6/8/2004.

Applicant's arguments filed 10/7/2004 have been fully considered but they are not persuasive.

Applicant notes that claim 14 indirectly depends on claim 6 and thus includes all the limitations thereof.

The relevance of this is not seen as the rejection is based on the rejection of claims 1-13 and 15-20 in further view of the secondary references. Claim 6 is part of the rejection above.

Applicant further asserts that, for the reasons set forth above, given the challenges in finding suitable chelating agent for actinium-225, it would not have been obvious to one of ordinary skill in the art to use the chelators disclosed by Wilson with actinium-225 and Scheinberg and/or Co do not teach chelating Ac-225 with the same chelators as claimed.

This is not found persuasive because Grifftihs and Geerlings teach the advantages of using Ac-225 in the same field of endeavor as the primary reference. Griffiths teaches that Ac-225 may be used with the same functional chelating agents as disclosed by Wilson, e.g., DOTA, while Geerlings teaches that Ac-225 is especially useful because of its emission properties and may be used with various chelates known in the art. Scheinberg and Co are relied upon for teaching that HuM195 specifically targets myeloid leukemia cells for radiotherapeutic treatment, e.g., AML, using an alpha emitter.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1616

11/18/2004